UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,911	06/07/2006	Naoko Kida	Q95279	8940

23373 7590 06/15/2009

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
06/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ATTACHMENT TO ADVISORY ACTION

Applicant has submitted art for consideration after final rejection in the form of an IDS filed 4/13/09 and three articles attached to their response but were not included in the IDS from Majumdar et al., Metzger et al., White et al. and Alhadlaq et al. The IDS filed 4/13/09 was not considered. The art of Majumdar et al., Metzger et al., White et al. and Alhadlaq et al. is specifically cited to support the Applicant's argument that **Mesenchymal Stem Cells** (**MSCs**) are unique in 2D culture and would not be cultured to confluence which is the suggested practice cited in Current Protocols in Cell Biology (1449, 11/24/08, Ref U). This reference was cited to rebut the Applicant's assertion that:

> "the confluent 2D culture prior to subculturing is out of the common general knowledge in the field of cell culture. A person skilled in the art normally subcultures the cells when the cells grow to 70 to 90% confluency. It is known in the art that, if the cells are cultured to 100% confluency, then the proliferation property of the cells may be affected or the phenotype of the cells may alter due to contact inhibition. Thus, it is atypical to conduct the confluent 2D culture prior to subculturing." (Applicant's Response 7-28-09)

The Applicant argues that the additional art of Majumdar et al., Metzger et al., White et al. and Alhadlaq et al. indicates that MSCs are an exception to the general protocol for mammalian cells taught by Current Protocols in Cell Biology. The Applicant has not provided a reason why this evidence was not previously submitted and it seems to contradict the Applicant's previous assertion cited above that cells in general are not cultured to confluence. Therefore this additional evidence will not be entered. Please refer to MPEP §§ 714.12 and 714.13 wherein it is stated that new evidence should not be entered unless Applicant provides “good and sufficient reasons” under 37 CFR § 1.116 or 37 CFR § 1.195 why they were not earlier presented. In the instant case, a first action was sent to Applicant with a rejection under 35 U.S.C. 103 wherein the Examiner made out a proper prima facie case. In response to Applicant’s argument and amendment, a final rejection was mailed to Applicant that maintains the claims as obvious and sufficiently rebuts Applicant’s arguments by pointing out that a prima facie case has been presented. Now, after final, applicant files new evidence to overcome the 35 U.S.C. 103 rejection. Applicant gives no reasons as to why this evidence was not earlier presented. Therefore the new evidence is not entered at this time and the arguments directed toward the new evidence are not considered either.

The argument that "the presently claimed invention aims to promote differentiation of the mesenchymal stem cells to form tissues" was addressed on page 4 of the Final Office Action (11/24/08).

The argument that the Goodwin #1, #2, #3 references do not teach the 2D to 3D culture as a single element is not considered since the claims do not contain this limitation. The argument that the Applicants method is superior to that disclosed by Goodwin #1, #2 and #3 because the current invention does not require a carrier was not considered because the claims do not contain this limitation.

Therefore the holding of obviousness in the Final Office Action (mailed 7/28/08) remains.

/Leon B Lankford/
Primary Examiner, Art Unit 1651